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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,547	10/26/2005	Harvey Kaplan	1658-8/AMK	1415

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EXAMINER	
AUDET, MAURY A	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,547	KAPLAN ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/14/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments and amendments are acknowledged. The Examiner thanks Applicant for the concise analysis of the invention, and identification of the vacuum step as the point of novelty, upon which the analysis below now turns.

The present application has been transferred from former Examiner Young to the present Examiner.

Election/Restrictions

As noted previously, Applicant's election without traverse of Group I, claims 1-6, in the reply filed on 4/16/07, is acknowledged. The remaining claims have been cancelled.

International Search Report

As noted previously, the International Authority searched/examined the identical claims 1-6 as presently elected. The Authority found three (3) references as each rendering obvious ("Y") claims 1-6:

1. BORATYNSKI teach: "Dry reaction of proteins with carbohydrates at 120 degrees C yield neoglycoconjugates" BIOTECHNOLOGY TECHNIQUES, vo1.12, no.9, Sept.1998 (1998-09), p.707-710, XP009022491 [NOTE: Could not be found on Medline Search];

2. BORATYNSKI, J. ET AL: "High temperature conjugation of proteins with carbohydrates" GLYCOCONJUGATE JOURNAL, vol. 15, no. 2, Feb. 1998 (1998-02), p. 131-138, XP009022617 (abstract); and

3. TARELLI EDWARD ET AL. "Lysine vasopressin undergoes rapid glycation in the presence

of reducing sugars" JOURNAL OF PHARMACEUTICAL & BIOMEDICAL ANALYSIS, vol.12, no.11, 1994, p.1355-1361, XP009022490 (abstract).

The latter two references are applied against the same claims 1-6 below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over TARELLI ET AL. (JOURNAL OF PHARMACEUTICAL & BIOMEDICAL ANALYSIS, vol.12, no.11, 1994, p.1355-1361, XP009022490), in view of BORATYNSKI (GLYCOCONJUGATE JOURNAL, vol. 15, no. 2, Feb. 1998 (1998-02), p. 131-138, XP009022617) is maintained for the reasons of record. Applicant's arguments have been considered but are not yet deemed persuasive.

Based on the knowledge of one of ordinary skill in the peptide glycating art, the skilled artisan was aware of vacuum techniques for glycating proteins. **Merely, by example, and not relied upon to maintain the obviousness of the present invention, Brodsky et al. (US 4,971,954) treach the glycating of collagen proteins from tendon under vacuum**:

> The solubilization of glycated tendon by CNBr was carried out as follows: about 10 mg wet tissue was treated with 1 ml of 70% formic acid containing 100 mg CNBr at 30.degree. C for 6 hr, and dried in vacuum over NaOH. After addition of 10 mM acetic acid with intensive mixing, centrifugation in an Eppendorf microcentrifuge yielded the CNBr soluble and insoluble fractions. These fractions were lyophilized and weighed.

Thus, based on the art recognized knowledge/techniques available to the skilled artisan, the vacuum step is not presently deemed to rise above the level of obviating the grounds of rejections, based on the references/knowledge in the art, as applied.

The rejection is repeated below for continuity of record:

TARELLI ET AL. teach that "lysine vasopressin undergoes rapid glycation in the presence of reducing sugars". The primary teachings of Tarelli et al. are that "*lysine vasopressin (LVP) readily reacts with reducing saccharides both in lyophilized preparations and in aqueous solution. Incubation of LVP with, for example, lactose over a pH range of 3.0-8.5* in phosphate buffer or simply in water [ ] analyzed by reversed-phase HPLC [ ] and by FAB mass-spectral analysis of derivatives isolated *after reduction with cyanoborohydride.* [ ]" (entire document, abstract). Tarelli et al. does not expressly teach a heating step following the lyophilization step in the protein glycosylation process therein.

BORATYNSKI teach "high temperature conjugation of proteins with carbohydrates", namely "a new procedure was used to conjugate lactose and de/xtran with BSA without using coupling or activating reagents. The method is *simple, rapid and cheap*. Reducing sugars covalently bind to proteins when *lyophilized together and briefly heated to a high temperature*" (entire document, abstract). [Note: The extremely broad limitations as to temperature, hours of heating, number of sugar units (claims 3-6) are deemed inherent in Boratynski II, absent evidence to the contrary.]

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to heat the lyophilized protein in the glycosylation process of Tarelli et al. because Boratynski. advantageously teach a protein glycosylation process whereby the lyophilized solution is heated thereafter, while Tarelli et al. teach all the other steps of the process including the use of a reducing agent such as cyanoborohydride. One of ordinary skill in the art in protein glycosylation would have been motivated to apply the heating step of Boratynski II to the Tarelli et al. glycosylation process, based on the advantages of shown by the former in a protein glycosylation process found to be simple, rapid and cheap – essential concerns for any lab/skilled artisan managing said lab.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 12/19/08

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654